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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,949	12/10/2003	Ilya Avrutov	1662/51203	6309

7590 11/15/2004

KENYON & KENYON  
Suite 700  
1500 K Street  
Washington, DC 20005

EXAMINER

LAMBKIN, DEBORAH C

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/730,949

Applicant(s)

AVRUTOV ET AL.

Examiner

Deborah C Lambkin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.


**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

  
DEBORAH C. LAMBKIN  
PRIMARY EXAMINER

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kammerer et al (US 4,284,786).

Kammerer et al teach the compound lefluomide having antirheumatic properties (see abstract).

Applicant is claiming a product by process which is a product claim, not a process claim. There is no patentable distinction seen between the instant product and that of the prior art. The structure of the compound is known and remains the same even though it contains more or less impurities. Furthermore, a purer product in and of itself does not necessarily impart patentability to an otherwise known product, absent some unobvious or unexpected result. One of ordinary skill in the art would expect a purer product to have more beneficial properties over its otherwise less purer counterpart.

No patentable distinction is seen between the instant product and that of the prior art.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

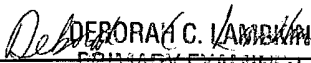
Claims 27-40 are rejected under 35 U.S.C. 102(a) as being anticipated by Faasch et al (6,060,494).

Faasch et al (6,060,494) teach a different crystal form of leflunomide which is useful for treating rheumatoid arthritis as well as proliferative disorders such as cancer (see abstract).

Likewise, as discussed above, there is no patentable distinction seen between the instant product and that of the prior art. A product by process claim is a product claim even though the process may be novel and unobvious. Furthermore, a product by process claim is usually used when the product cannot be described in any other way or when the structure is unknown, in which neither is the case here. Leflunomide has a definite structure, N-(4-trifluoromethylphenyl)-5-methylisoxazole-4-carboxamide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah C. Lambkin whose telephone number is 571-272-0698.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699.

  
DEBORAH C. LAMBKIN  
PRIMARY EXAMINER  
Deborah C. Lambkin  
Primary Patent Examiner